UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/325,095	06/03/1999	IAN D. HILES	LUD5246.4JEL	2392

24972 7590 01/29/2008
FULBRIGHT & JAWORSKI, LLP
666 FIFTH AVE
NEW YORK, NY 10103-3198

EXAMINER	
HINES, JANA A	
ART UNIT	PAPER NUMBER
1645	
MAIL DATE	DELIVERY MODE
01/29/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte
IAN D. HILES, MICHAEL J. FRY, RITU DHAND, MICHAEL D. WATERFIELD, PETER J. PARKER, MASAYUKI OTSU, GEORGE PANAYOUTOU, STEFANO VOLINIA, and IVAN GOUT

Appeal 2007-2728
Application 09/325,095
Technology Center 1600

DECIDED: January 29, 2008

Before TONI R. SCHEINER, DONALD E. ADAMS, and DEMETRA J. MILLS, *Administrative Patent Judges*.

SCHEINER, *Administrative Patent Judge*.

DECISION ON APPEAL

Appellants appeal under 35 U.S.C. § 134 from a final rejection of claims 50-58, 60, and 61, the only claims remaining in the application. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

DISCUSSION

The claims have been rejected under 35 U.S.C. § 112, first paragraph, as lacking adequate written descriptive support in the Specification as filed (Ans. 4). This is a new matter rejection.[1]

Claim 51 is representative:

> 51. A method for determining expression of a gene which encodes a human polypeptide that has PI3 kinase activity and a molecular weight of about 110 kil[o]daltons as determined by SDS-PAGE, comprising contacting a sample with a nucleic acid molecule which hybridizes specifically to a transcript of said gene wherein said transcript is RNA or cDNA, and is selected from the group consisting of (a) the nucleotide sequence set forth in SEQ ID NO:32; (b) the nucleotide sequence set forth in SEQ ID NO:35; and (c) the nucleotide sequence which hybridizes to the complement of at least one of (a) and (b), at 1MNaCl, 10xDenhardt's solutions; 50mM Tris-HCL (pH 7.4); 10mM EDTA; 0.1%SDS; 100µg/ml denatured herring sperm DNA at 65°C for 16 hours, followed by a wash of 2XSSC; 0.1%SDS at 42°C, or a wash of 0.5XSSC/0.1% SDS at 50°C, or a wash at 0.1XSSC/0.1%SDS at 65°C, or a wash at 0.1XSSC/0.1% SDS, at 68°C and determining said hybridization as a determination of expression of said gene.

Thus, the claims are directed to a method of determining expression of a gene encoding a polypeptide, designated p100, that has phosphoinositide (PI3) kinase activity, by detecting hybridization of nucleic acids with an RNA or cDNA transcript of the gene (SEQ ID NOS: 35 and 32) in a sample, under specified conditions.

---

[1] Three other rejections of the claims, one under 35 U.S.C. § 112, first paragraph, and two under 35 U.S.C. § 112, second paragraph, have been withdrawn by the Examiner (Ans. 3-4).

The Examiner acknowledges that "[t]he specification teaches hybridization and Polymerase Chain Reaction (PCR) techniques" (Ans. 6), but contends they are "not used with a method for determining gene expression" (*id.* at 7), but "in a completely different context, such as for gene cloning" (*id.* at 6), and "detection of specific nucleotide sequences" (*id.* at 7). Essentially, the Examiner argues that the Specification does not explicitly describe "determining hybridization as an act for the determination of gene expression" (*id.* at 11).

The purpose of the written description requirement is to "ensure that the scope of the right to exclude, as set forth in the claims[,] does not overreach the scope of the inventor's contribution to the field as far as described in the patent specification." *Reiffin v. Microsoft Corp.*, 214 F.3d 1342, 1345 (Fed. Cir. 2000). To satisfy the requirement, the Specification need not contain the identical words used in the claims. *See Purdue Pharma L.P. v. Faulding, Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000). Rather, the Specification must "convey with reasonable clarity to those skilled in the art that, as of the filing date sought, [Applicant] was in possession [of] . . . *whatever is now claimed*." *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1564 (Fed. Cir. 1991).

After reviewing the Specification, we are persuaded that it reasonably conveys possession of the claimed invention to those of skill in the art, as of the filing date of the application. Merely by way of example, we note that the Specification describes "[a] northern blot analysis carried out on mRNA isolated from the SGBAF-1 cell line and total bovine brain" (Spec. 46: 25-26) to detect "[e]xpression of p110" (*id.* at 46: 24). "Both mRNA samples

[were found to] contain major p110 specific transcripts" (*id.* at 46: 27). In addition, PCR "was performed to examine the distribution and conservation of p110 mRNA in cell lines and tissue from several species" (*id.* at 46: 31-33), including humans (*id.* at 46: 34). The transcription of DNA into mRNA is a necessary step in gene expression. Moreover, northern blot analysis, developed in 1977, is well known in the art as "a gold standard for the direct study of gene expression at the level of mRNA (messenger RNA transcripts)" (*see e.g.,* http://www.molecularstation.com/rna/northern-blot/ (accessed January 11, 2008)).

We find that one skilled in the art would have recognized from the Specification that Appellants were in possession of a method of determining expression of the gene encoding p110 by detecting hybridization of a nucleic acid with an RNA or cDNA transcript of the gene.

Accordingly, we reverse the Examiner's rejection of claims 51-58, 60, and 61 under 35 U.S.C. § 112, first paragraph, as lacking adequate written descriptive support in the Specification as filed.

REVERSED

lp

FULBRIGHT & JAWORSKI, LLP
666 FIFTH AVE
NEW YORK NY 10103-3198